UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAKE CHARLES DIVISION

RHONDA BREAUX	**CASE NO. 2:23-CV-01365**
VERSUS	**JUDGE JAMES D. CAIN, JR.**
NOVO NORDISK INC ET AL	**MAGISTRATE JUDGE KAY**

MEMORANDUM RULING

Before the court is a Motion to Dismiss [doc. 22] filed under Federal Rule of Civil Procedure 12(b)(6) by defendants Novo Nordisk U.S. Holdings Inc.; Novo Nordisk U.S. Commercial Holdings Inc.; Novo Nordisk Inc.; Novo Nordisk Research Center Seattle, Inc.; and Novo Nordisk Pharmaceutical Industries LP (collectively, "Novo Nordisk").[1] Plaintiff opposes the motion. Doc. 24.

I. BACKGROUND

This products liability suit arises from plaintiff's use of Ozempic (semaglutide), an injectable prescription medication that has been approved by the FDA for control of blood sugar in adults with Type 2 diabetes. The medication belong to a class of drugs called GLP-1 (glucagon-like peptide-1) receptor antagonists. Doc. 1, ¶¶ 29–33. Plaintiff, an adult resident of Louisiana, took Ozempic for approximately two months, stopping around October 2022. *Id.* at ¶¶ 8–10. She alleges that her use of this drug caused her to suffer from

[1] Novo Nordisk A/S and Novo Nordisk North America Operations A/S were both named as defendants but, as of the filing of this motion, had not been served. Accordingly, they did not join in the motion.

gastroparesis, a condition in which "the stomach's motility is slowed down or does not work at all, preventing the stomach from emptying properly" and potentially causing severe gastrointestinal complications. Plaintiff alleges that she experienced:

> severe vomiting, stomach pain, gastrointestinal burning, being hospitalized for stomach issues on several occasions including visits to the emergency room, and violent vomiting, requiring additional medications to alleviate her extreme and violent vomiting, and throwing up whole food hours or even days after eating.

Id. at ¶ 13. She further alleged that defendants "acknowledge that gastrointestinal events are a well known side effect of the GLP-1 class" but have "downplayed the severity of the gastrointestinal events" and "never . . . warn[ed] of the risk of gastroparesis[.]" *Id.* at ¶ 6.

Plaintiff filed suit in this court on September 29, 2023, against various Novo Nordisk entities (manufacturers of Ozempic). She raises claims of failure to warn and breach of express warranty under the Louisiana Products Liability Act ("LPLA"), La. R.S. 9:2800.52 *et seq.* She requests compensatory and punitive damages as well as attorney fees. Novo Nordisk now moves to dismiss the claims raised against it, arguing that (1) plaintiff's first amended complaint is a "shotgun pleading" that does not satisfy Rule 8, (2) plaintiff fails to adequately plead a cause of action for inadequate warning, (3) plaintiff fails to adequately plead a cause of action for breach of express warranty, and (4) plaintiff's claims for punitive damages and attorney fees should be dismissed because these are not available under the LPLA. Doc. 54, att. 1. Plaintiff opposes the motion in all respects. Doc. 24.

II.
LEGAL STANDARD

Rule 12(b)(6) allows for dismissal when a plaintiff "fail[s] to state a claim upon which relief can be granted." When reviewing such a motion, the court should focus on the complaint and its attachments. *Wilson v. Birnberg*, 667 F.3d 591, 595 (5th Cir. 2012). The Court can also consider documents referenced in and central to a party's claims only if plaintiffs do not object. *Scanlan v. Texas A&M Univ.*, 343 F.3d 533, 536 (5th Cir. 2003). Courts "may also consider matters of which [it] may take judicial notice." *Hall v. Hodgkins*, 305 Fed. App'x 224, 227 (5th Cir. 2008) (internal citation omitted) (quoting *Lovelace v. Software Spectrum Inc.*, 78 F.3d 1015, 1017–18 (5th Cir.1996) (unpublished opinion)).

Such motions are reviewed with the court "accepting all well-pleaded facts as true and viewing those facts in the light most favorable to the plaintiff." *Bustos v. Martini Club, Inc.*, 599 F.3d 458, 461 (5th Cir. 2010). However, "the plaintiff must plead enough facts 'to state a claim to relief that is plausible on its face.'" *In re Katrina Canal Breaches Litig.*, 495 F.3d 191, 205 (5th Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Accordingly, the court's task is not to evaluate the plaintiff's likelihood of success but instead to determine whether the claim is both legally cognizable and plausible. *Lone Star Fund v. (U.S.), L.P. v. Barclays Bank PLC*, 594 F.3d 383, 387 (5th Cir. 2010).

III.
LAW & ANALYSIS

A. Shotgun Pleading

Novo Nordisk asserts that the First Amended Complaint should be dismissed in its entirety because it is a "shotgun pleading"—that is, "a complaint that substitutes

generalities, broad allegations, and group pleading" in place of the "short and plain statement" showing her entitlement to relief that is required under Rule 8. To this end it focuses on potentially irrelevant factual allegations, including allegations that involve another GLP-1 RA, Mounjaro (tirzepatide), that plaintiff has not alleged she ever took, and allegations relating to Novo Nordisk's marketing campaign for Ozempic. It also emphasizes plaintiff's failure to allege certain facts, such as

> when or where Plaintiff was first prescribed Ozempic, who prescribed Ozempic to her, whether the prescribing physician(s) had knowledge of Ozempic's label and whether they were aware of its disclosed gastrointestinal side effects, when her gastrointestinal side effects allegedly began and when they resolved, what medication she was taking when the side effects started, or where or when she received treatment (if any) for those side effects.

Doc. 22, att. 1, p. 15.

The inclusion of information related to Mounjaro in two paragraphs appears to be an error but does not warrant dismissal or amendment of the complaint. As for the allegations relating to the marketing of Ozempic, courts in this circuit have held in relation to express warranty claims that a manufacturer may not "suppress information and make false representations of superiority and efficacy when gaining significant market share with a defective product." *Kennedy v. Pfizer, Inc.*, 2013 WL 4590331, at *6 (W.D. La. Aug. 28, 2013). Accordingly, allegations relating to Ozempic's rapid rise in the market are potentially relevant to a breach of express warranty claim. Finally, plaintiff has alleged that she developed gastroparesis and its sequelae as a result of using Ozempic over roughly a two-month time period concluding in October 2022. She has also alleged, as described infra, that she was prescribed the drug by her physician(s) and that her doctor did not know

of the gastroparesis risk associated with the drug. Issues such as when she developed her symptoms, who her physician was, and what their subjective awareness was of all the drug's potential side effects "constitute topics for discovery, not Rule 8 pleading requirements" and should be deferred to a motion for summary judgment or trial on the merits. *Lewis v. GE Healthcare, Inc.*, 2020 WL 1490719, at *7 (W.D. La. Mar. 25, 2020) (DOUGHTY, C.J.); *see also Baudin v. AstraZeneca Pharmaceuticals LP*, 413 F.Supp.3d 498, 509–10 & n. 13 (M.D. La. 2019) (plaintiff not required to identify prescribing physician at pleading stage). Accordingly, the motion will be denied on this basis.

B. Inadequate Warning Claim

Novo Nordisk next argues that plaintiff has not stated a plausible claim of failure to warn, in light of Louisiana's learned intermediary doctrine. This doctrine holds that a drug manufacturer discharges its duty to consumers by reasonably informing prescribing physicians of the risks associated with a drug. *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 265 (5th Cir. 2002) (citing *Anderson v. McNeilab, Inc.*, 831 F.2d 92, 93 (5th Cir. 1987)). Accordingly, plaintiff must allege facts showing (1) "that the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product that was not otherwise known to the physician" and (2) "that this failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury." *Id.* at 265–66. The learned intermediary doctrine is an affirmative defense on which defendant bears the burden of proof. *Brocato v. DePuy Orthopaedics, Inc.*, 2015 WL 854150, at *6 (E.D. La. Feb. 25, 2015) (citing *Ebel v. Eli Lilly and Co.*, 536 F.Supp.2d 767, 772 (S.D. Tex. 2008)).

Plaintiff has alleged, *inter alia*, (1) that she was prescribed Ozempic by her physician(s), (2) that the labels and promotional materials did not disclose the risk of gastroparesis as an adverse reaction and thus failed to adequately warn plaintiff's physician(s) of this risk, and (3) that plaintiff's physician(s) would not have prescribed Ozempic if they had been warned of the risk or would have given plaintiff additional information in order to make an informed decision regarding her use of these drugs, which would have caused her not to use the drugs and thereby avoid the side effects she has suffered. Doc. 1, ¶¶ 11, 70–72, 80, 99–103, 106–08. Novo Nordisk maintains that these allegations are insufficient because (1) plaintiff fails to allege adequate facts to show causation and (2) plaintiff fails to show a breach of any duty of care by Novo Nordisk, because the asserted risks were disclosed on the label and well-known in the medical literature.

At the pleading stage, a plaintiff is not required "to detail what an adequate warning would be and how an adequate warning would have caused [his] treating physician to act differently." *Baudin*, 413 F.Supp.3d at 510 (quoting *Jenkins v. Bristol-Myers Squibb*, 2015 WL 5012130 (E.D. La. Aug. 21, 2015)). Here plaintiff admits that the then-existing labels contained (1) information about a "minor delay in gastric emptying" in the "Mechanism of Action" section, (2) a warning of delayed gastric emptying that might impact absorption of orally administered drugs in the "Drug Interaction" section, and (3) other gastrointestinal conditions such as "nausea, vomiting, diarrhea, abdominal pain, and constipation," which are symptoms of gastroparesis, as potential adverse events. Doc. 1, ¶¶ 72, 77. She maintains, however, that the warning was inadequate because it failed to include

gastroparesis as an adverse event/risk of taking Ozempic, any indication of the potential severity of the listed gastrointestinal adverse events, or that the drug had not been adequately tested for safety risks, including gastroparesis. *Id.* at ¶¶ 99–104. She also alleges that, if equipped with an adequate warning, her physician would not have prescribed the medication. *Id.* at ¶ 107. Support for or against this claim will depend on evidence outside the scope of these pleadings and the parties' briefs. At the motion to dismiss stage, however, she has set forth a plausible claim for relief.

C. Express Warranty Claim

Novo Nordisk next asserts that plaintiff fails to adequately plead the elements of a breach of express warranty claim. As to express warranties, the LPLA provides:

> A product is unreasonably dangerous when it does not conform to an express warranty made at any time by the manufacturer about the product if the express warranty has induced the claimant or another person or entity to use the product and the claimant's damage was proximately caused because the express warranty was not true.

La. R.S. § 9:2800.58. To maintain a claim under this portion of the LPLA, a plaintiff must show: "(1) the manufacturer made an express warranty regarding the product, (2) the plaintiff was induced to use the product because of that warranty, (3) the product failed to conform to that express warranty, and (4) the plaintiff's damage was proximately caused because the express warranty was untrue." *Caboni v. Gen. Motors Corp.*, 278 F.3d 448, 452 (5th Cir. 2002). An express warranty is "a representation or statement about a product that affirms the product possesses specified characteristics or qualities." *Guidry v. Janssen Pharm., Inc.*, 206 F.Supp.3d 1187, 1199 (E.D. La. 2016) (citing La. R.S. § 9:2800.53(6)). For pharmaceuticals, marketing materials may rise to the level of an express warranty if

they make claims as to the product's safety. *Boutte v. Stryker Biotech, LLC*, 67 F.Supp.3d 732, 738–39 (W.D. La. 2014). A plaintiff is not required to "point to specific language offered by a manufacturer," but must still "specify the warranty in question" to state a claim for relief. *Fuller v. Eisai Inc.*, 513 F.Supp.3d 710, 722 (E.D. La. 2021) (internal quotations omitted).

The complaint contains several paragraphs relating to the marketing of Ozempic. These allegations include Novo Nordisk's announcement of the FDA's approval of semaglutide, its promotion of the drug's "safety and sale of Ozempic" through an $884 million ad campaign along with $11 million spent on food and travel to promote the drug to physicians, and Ozempic's resulting surge in popularity. *Id.* at ¶¶ 33–44. Under her breach of warranty claim, plaintiff alleges that the labels and other communications made by defendant to plaintiff and her prescribing physicians warranted that Ozempic and Mounjaro "were safe as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus." *Id.* at ¶ 121. She further alleges that she would not have used/would not have been prescribed Ozempic but for these guarantees and thus would not have suffered gastroparesis or its sequelae. *Id.* at ¶¶ 123–40. She fails to identify any representations[2] amounting to specific promises about the product's safety, however. This omission is fatal to her claim.

[2] The only specific statement about safety quoted in the complaint comes from a March 2022 press release, mentioning the drug's "proven safety" after a clinical trial of a higher dose of Ozempic. Doc. 1, ¶ 33; *see Novo Nordisk receives FDA approval of higher-dose Ozempic 2 mg providing increased glycemic control for adults with type 2 diabetes*, Cision PR Newswire (March 28, 2022), available at https://www.prnewswire.com/news-releases/novo-nordisk-receives-fda-approval-of-higher-dose-ozempic-2-mg-providing-increased-glycemic-control-for-adults-with-type-2-diabetes-301512209.html (last visited December 11, 2023). This is not included in the factual allegations relating to Novo Nordisk's promotion of the drug, however, and plaintiff's express warranty allegations—premised on an ad campaign that began well before this press release and continued long after—appear too broad to stem from this lone

As several district courts have affirmed, general allegations that the manufacturer has warranted the product as "safe" are too vague to support a claim under the LPLA. *E.g.*, *Fuller*, 513 F.Supp.3d at 723 (conclusory allegations of representations that drug was "safe" and "effective to use" did not rise to the level of a warranty under the LPLA); *see also Corley v. Stryker Corp.*, 2014 WL 3375596, at *5 (W.D. La. May 27, 2014), report and recommendation adopted *sub nom. Corley v. Stryker Orthopaedics*, 2014 WL 3125990 (W.D. La. Jul 3, 2014) (paraphrased guarantee that product "was effective and safe for its intended use" did not qualify as an express warranty); *Lewis v. Baxter Int'l Inc.*, 2017 WL 661324, at *5 (E.D. La. Feb. 17, 2017) (dismissing express warranty claim premised on alleged guarantee that product was "suitable and safe for use"); *accord Aston v. Johnson & Johnson*, 248 F.Supp.3d 43, 55 (D.D.C. 2017); *Fraser v. Wyeth, Inc.*, 857 F.Supp.2d 244, 257–58 (D. Conn. 2012); *In re Meridia Prods. Liab. Litig.*, 328 F.Supp.2d 791, 818 (N.D. Ohio 2004). Context is important, because the disclaimers and disclosures frequently attached to affirmations of safety for prescription drugs may eliminate an express warranty claim. *E.g.*, *In re Avandia Marketing Sales Practices & Prods. Liab. Litig.*, 588 F. App'x 171, 175–76 (3rd Cir. 2014). Here, plaintiff's allegations amount to a general statement that the product was advertised in some capacity as safe for its intended use. This does not provide enough factual information for the court to determine whether an express warranty was made, sufficient to induce plaintiff's reliance, and cannot support a claim for breach.

statement. *See* doc. 1, ¶ 122 ("The aforementioned express warranties were made to Plaintiff and Plaintiff's prescribing physician by way of Ozempic's label, website, advertisements, promotional materials, **and** through other statements.") (emphasis added). If the press release forms the basis of plaintiff's express warranty claim, it must be amended at any rate to remove the irrelevant allegations and provide defendant with appropriate notice.

Accordingly, the motion will be granted on this basis. This ruling is without prejudice to plaintiff's right to amend within 30 days if she can allege a sufficient basis for an express warranty.

D. Punitive Damages and Attorney Fees

Finally, Novo Nordisk asserts that plaintiff's claim for punitive damages and attorney fees should be dismissed. Under Louisiana law, punitive damages are only allowed where expressly authorized by statute. *Bladen v. C.B. Fleet Holding Co.*, 487 F.Supp.2d 759, 770 (W.D. La. 2007) (citing *Int'l Harvester Credit Corp. v. I.T. Seale*, 518 So.2d 1039, 1041 (La. 1988)). The LPLA makes no such provision. *Id.* Likewise, under "the bedrock principle known as the American Rule," each litigant is responsible for his own fees "unless a statute or contract provides otherwise." *Baker Botts LLP v. ASARCO LLC*, 576 U.S. 121, 126 (2015) (internal quotations omitted). The LPLA also makes no provision as to recovery of attorney fees. *Chevron USA, Inc. v. Aker Maritime, Inc.*, 604 F.3d 888, 900 (5th Cir. 2010). Proceeding under Louisiana law, plaintiff has no claim for punitive damages or attorney fees.

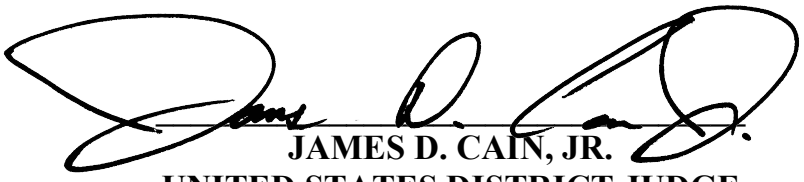
Plaintiff concedes that Louisiana law should govern liability but argues that the court should reserve judgment in case it finds that another state's law applies to damages. Louisiana's choice of law statutes permit the application of different states' laws to different issues in a case, a practice known as dépeçage. *PHI, Inc. v. Apical Indus., Inc.*, 2021 WL 67726, at *7 & n. 45 (W.D. La. Jan. 7, 2021) (citing La. C.C. art. 3515, cmt. (d)). The decision depends on the "totality of the circumstances." *Duhon v. Union Pac.*, 43 F.3d

1101, 1018 (5th Cir. 1995). Accordingly, the court agrees that any such determination is premature at this time and must await a motion for summary judgment.

IV.
CONCLUSION

For the reasons stated above, Novo Nordisk's Motion to Dismiss [doc. 22] will be **GRANTED** as to the express warranty claim and **DENIED** in all other respects.

THUS DONE AND SIGNED in Chambers on the 12th day of December, 2023.



JAMES D. CAIN, JR.
UNITED STATES DISTRICT JUDGE